

TYPE ABSTRACT WITHIN BOX

Pramlintide, an Analog of Human Amylin
Improves Glycemic Control in Patients with Type
II Diabetes Requiring Insulin.

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The effects of 4 weeks of subcutaneous administration of pramlintide, (Pr) an analog of human amylin, on glycemic control in 203 patients with Type II diabetes mellitus requiring insulin were examined in a randomized, double-blind, placebo-controlled, parallel-group trial. Statistically significant reductions in serum fructosamine concentration were observed in the Pr 30 µg QID group (17.5 ± 4.9 µmol/L), the Pr 60 µg TID group (24.1 ± 4.9 µmol/L) and the Pr 60 µg QID group (22.6 ± 4.1 µmol/L) compared to placebo (PBO) (3.5 ± 3.8 µmol/L). There also were statistically significant shifts in the proportion of patients with an abnormal serum fructosamine concentration at baseline that normalized at Week 4 within the Pr 60 µg TID group (28%) and the Pr 60 µg QID group (31%) compared to PBO (10%). Consistent with the reduction in fructosamine, there were also statistically significant reductions in HbA_{1c} in the Pr 30 µg QID group ($0.53 \pm 0.07\%$), the Pr 60 µg TID group ($0.58 \pm 0.07\%$) and the Pr 60 µg QID group ($0.51 \pm 0.08\%$) compared to placebo ($0.27 \pm 0.08\%$). Based on RBC lifespan, and assuming stable glycemic control, these reductions in HbA_{1c} in the Pr groups should increase over the following 2-3 months. The reductions in fructosamine and HbA_{1c} were accompanied by a statistically significant reduction in fasting total and LDL cholesterol. In contrast to treatment with insulin alone, there were trends towards decreased body weight in the Pr 60 µg TID and 60 µg QID groups. Furthermore, the incidence of hypoglycemia was no greater in any Pr group than in placebo. In conclusion, measurement of similar changes in both serum fructosamine concentration and HbA_{1c} suggests that pramlintide therapy for 28 days improves glycemic control in patients with Type II diabetes mellitus requiring insulin.

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